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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,853	12/30/2003	Carl J. Wheeler	CA1818	6433

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Sughrue Mion , PLLC
2100 Pennsylvania Avenue, N.W.
Washington, DC 20037

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
08/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com

Office Action Summary	Application No.	Applicant(s)	
	10/748,853	WHEELER, CARL J.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2010 and 26 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68,71,73,74 and 85-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68,71,73,74 and 85-87* is/are rejected.

7)☒ Claim(s) *86* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 68, 71, 73-74 and 85-87 are presented for examination.

Applicant's Amendment filed January 4, 2010 was received and entered into the present application. Pursuant to the notice dated April 27, 2010, the submission dated January 4, 2010 was non-compliant. Applicant's subsequent amendment correcting these deficiencies filed May 26, 2010 has been received and entered into the present application.

Claims 68, 71, 73-74 and 85-87 remain pending and under examination. Claims 68, 71, 73 and 85-86 are amended. Claim 72 is cancelled.

Applicant's arguments, filed January 4, 2010 and May 26, 2010, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Objection to the Claims (New Grounds of Objection)

Claim 86 is objected to for failing to define the acronyms "DORIE" and "DMRIE" at their first occurrence in the claim. Correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 86 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The parenthetical statements present in instant claim 86 render the claim indefinite because it is unclear what limiting effect such statements have on the claim. It is unclear whether such statements are

alternative names of the compounds or whether they are part of the chemical name of the recited compound. This is further complicated by the fact that Applicant has seemingly presented some of the parenthetical statements as definitions of claimed acronyms (e.g., DORIE carboxylate, which appears to be dioleyl rosenthal inhibitor ether carboxylate) and others as ambiguous limitations whose effect on the claimed subject matter is not clear (e.g., DMRIE carboxylate (methionine-leucine-methylester) amide). Clarification is required, since it is unclear what compounds are, in fact, intended to be circumscribed by the instant claim. Accordingly, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the metes and bounds of subject matter for which Applicant is presently seeking protection.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and is, thus, properly rejected.

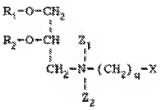
Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 68, 71, 73-74, 85 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jessee (WO 95/02698; Published January 1995) in view of Felgner (WO 91/17424; 1991).

Jessee teaches compositions of cationic lipids and viral components that are useful for transfecting eukaryotic cells with nucleic acids (which are large anionic molecules; p.1, p.12-16) and also for the introduction of other macromolecules into such cells (abstract), wherein the cationic lipid



compounds have the following chemical structure: (p.19, l.22-33), wherein R_1 and R_2 are separately, *inter alia*, C_{1-23} alkyl (i.e., which corresponds to Applicant's instantly claimed R_1 and R_2 groups $C_{14}H_{29}$ or $C_{12}H_{25}$ as in instant claims 68 and 71 or the R_1 and R_2 groups of instant claim 85), q is 1-6 (i.e., which corresponds to Applicant's instantly claimed m that may be 1-10), Z_1 and Z_2 are separately, *inter alia*, hydrogen or an unbranched alkyl group of 1-6 carbon atoms (i.e., which correspond to Applicant's instantly claimed R_3 and R_4 groups that may be hydrogen or C_{1-23} alkyl as in instant claims 68 or 71 or may be C_{1-5} alkyl groups as in instant claim 73 or may be methyl groups as in instant claim 74) and X may be selected from, *inter alia*, carboxyspermine (i.e., which is understood to be a teaching that the carboxy-terminus of the carboxyspermine is attached to the methylene chain $(CH_2)_q$ since it is named first, which also meets Applicant's requirement that R_5 has the structure $-C(=O)-Z-R_6$, wherein Z is nitrogen, since the $-Z-R_6$ group would be the spermine chain attached to the carboxy terminus of $-C(=O)$ as recited in instant claim 68 or Applicant's requirement that R_5 has the structure $-C(=O)-N-R_7R_8$, wherein the R_7 and R_8 group would be the spermine chain, which would comprise a hydrogen from the terminal end of the spermine chain as R_7 and the remainder of the spermine chain as R_8, which is provided for in the instant claims as "other bioactive or pharmaceutical agent" as in instant claim 71; p.19, l.33-40).

Note also that it is understood that, in order to attach the carboxyspermine compound to the end of the methylene group of the remainder of the cationic compound, the compounds would be reacted so as to remove water via the attachment of a hydrogen from the alkyl group at the end of the compound with the -OH group of the carboxyspermine compound such that the carbonyl group of the carboxyspermine compound would be attached directly to the end of the methylene group of the cationic compound (i.e., $-CH_2-C(=O)-$), absent factual evidence to the contrary.

Jessee fails to explicitly teach the step of combining the disclosed cationic lipid compounds with an anionic molecule to deliver the anionic molecule into a cell (claims 68, 71 or 85).

Felgner teaches that cationic lipid technology using positively charged synthetic cationic lipids in the form of liposomes, or small vesicles, is capable of interacting spontaneously with DNA, which is negatively charged, or anionic, to form lipid-DNA complexes having a net positive charge and are capable of fusing with the negatively charged cell membranes of tissue culture cells to achieve both uptake and expression of the DNA by said cells (p.2, l.28-p.3, l.3). Felgner further teaches that valuable therapeutic agents are most effective in influencing cell function at the subcellular or molecular levels (such as, e.g., natural biological molecules and their analogues or foreign substances, such as drugs) and are, therefore, preferably incorporated into the cell in order to produce their effect (p.1, l.13-24). Still further, Felgner discloses that intracellular delivery of bioactive agents is particularly useful for, e.g., introducing expressible DNA and mRNA into the cells of a mammal to effect intracellular delivery of beneficial or interesting proteins (p.2, l.1-8).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to employ the cationic lipid compounds as disclosed by Jessee, which are expressly taught to be useful for binding and transporting polynucleotides, polypeptides, pharmaceutical substances and other biologically active species through membrane barriers, in the form of liposomes and combining such liposomes with anionic DNA (i.e., an "anionic molecule" as instantly claimed; see, e.g., instant claim 68) to form a lipid-DNA complex with a net positive charge to elicit the predictable result of fusing with the negatively charged cell membranes of tissue culture cells to transfect such DNA into the cell such that the cell then expresses the DNA. Such a person would have been clearly motivated to do so in order to predictably effect the intracellular delivery of expressible DNA into cells to produce proteins of interest (e.g., proteins of therapeutic value or proteins of experimental value, etc.).

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that the amendments to the claims clarify the subject matter and obviate the instant rejections over the cited prior art. Applicant references the arguments acknowledged in the final Office Action dated January 29, 2009 in response to the rejections.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

The amendments to the claims have been noted, but for the reasons *supra*, and those previously of record, Jessee in view of Felgner teaches compounds and methods identical to Applicant's instant claims. Applicant has failed to advance any particular reasons to support his position that the cited prior art does not meet the instant claims and, thus, amounts to a mere allegation of patentability without any supporting evidence or reasoning. This is unpersuasive, particularly in view of the factual teachings of the cited prior art as summarized *supra*.

In addition, Applicant's reference to previously submitted arguments has been noted, but fails to be persuasive because Jessee was first applied in the immediately prior Office Action dated August 4, 2009 and, therefore, any arguments previously submitted were directed to other references of record, not the Jessee reference. Thus, such arguments fail to be persuasive in establishing nonobviousness over this reference newly made of record in the last Office Action.

Accordingly, in the absence of any substantive remarks submitted by Applicant, the rejection over the cited prior art of Jessee in view of Felgner is proper for the reasons *supra*.

Conclusion

Rejection of claims 68, 71, 73-74 and 85-87 is proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Primary Examiner, Art Unit 1614

July 27, 2010